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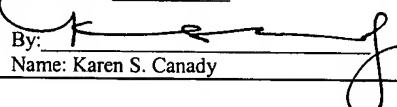
Due Date: June 28, 2001

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Luigi Naldini et al. Examiner: To Be Assigned  
Serial No.: 10/031,639 Group Art Unit: To Be Assigned  
Filed: October 29, 2001 Docket: G&C 131.3-US-WO  
Title: METHOD AND MEANS FOR PRODUCING HIGH TITER, SAFE, RECOMBINANT  
LENTIVIRUS VECTORS

CERTIFICATE OF MAILING OR TRANSMISSION UNDER 37 CFR 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on June 26, 2002.

By:   
Name: Karen S. Canady

Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

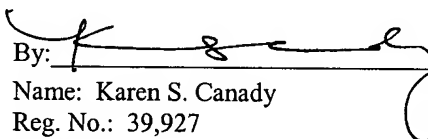
We are transmitting herewith the attached:

- ☒ Transmittal sheet, in duplicate, containing a Certificate of Mailing under 37 CFR 1.8.
- ☒ Information Disclosure Statement and Form PTO-1449.
- ☒ Cited Reference(s).
- ☒ Return postcard.

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers, if appropriate.

Please charge any additional fees or credit any overpayment to Deposit Account No. 50-0494 of Gates & Cooper LLP. A duplicate of this paper is enclosed.

Customer Number 22462  
**GATES & COOPER LLP**  
Howard Hughes Center  
6701 Center Drive West, Suite 1050  
Los Angeles, CA 90045  
(310) 641-8797

By:   
Name: Karen S. Canady  
Reg. No.: 39,927  
KSC/kmf

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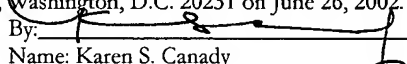
(PTO TRANSMITTAL - GENERAL)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Luigi Naldini et al. Examiner: To Be Assigned  
Serial No.: 10/031,639 Group Art Unit: To Be Assigned  
Filed: October 29, 2000 Docket: G&C 131.3-US-WO  
Title: METHOD AND MEANS FOR PRODUCING HIGH TITER, SAFE,  
RECOMBINANT LENTIVIRUS VECTORS

CERTIFICATE OF MAILING OR TRANSMISSION UNDER 37 CFR 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on June 26, 2002.

By:   
Name: Karen S. Canady

INFORMATION DISCLOSURE STATEMENT (37 C.F.R. §1.97(b))

Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner.

This statement should be considered because it is submitted before the mailing date of a first Office Action on-the-merits. Accordingly, no fee is due for consideration of the items listed on the enclosed Form 1449.

In accordance with 37 C.F.R. §1.98(a)(2), a copy of each document or other information listed on the enclosed Form 1449 is provided.

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the reference(s) are not "prior art". Moreover, Applicants do not represent that a reference has been thoroughly reviewed or that any relevance of any portion of a reference is intended.

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Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form 1449, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

Please direct any response or inquiry to the below-signed attorney at (310) 641-8797.

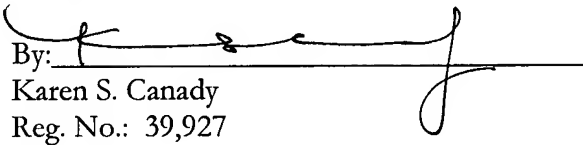
Respectfully submitted,

GATES & COOPER LLP  
Attorneys for Applicant(s)

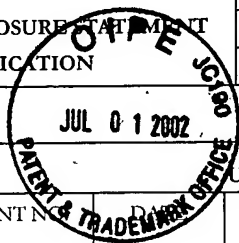
Howard Hughes Center  
6701 Center Drive West, Suite 1050  
Los Angeles, California 90045  
(310) 641-8797

Date: June 26, 2002

KSC/kmf

By:   
Karen S. Canady  
Reg. No.: 39,927

<b>Form 1449*</b> <b>INFORMATION DISCLOSURE STATEMENT</b> <b>IN AN APPLICATION</b>	Docket Number: G&C 131.3-US-WO	Application Number: 10/031,639
	Applicant: Luigi Naldini et al.	
	Filing Date: October 29, 2001	Group Art Unit: To Be Assigned



U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,503,974	04/02/96	Gruber et al.			
	5,583,022	12/10/96	Heidmann et al.			
	5,591,579	01/07/97	Olivo et al.			
	5,614,404	03/25/97	Mazzara et al.			
	5,650,309	07/22/97	Wong-Staal et al.			
	5,665,577	09/09/97	Sodroski et al.			
	5,681,746	10/28/97	Bodner et al.			
	5,693,508	12/02/97	Chang			
	5,716,613	02/10/98	Guber et al.			
	5,716,826	02/10/98	Gruber et al.			
	5,739,118	04/14/98	Carrano et al.			
	5,747,307	05/05/98	Lever et al.			
	5,994,136	11/30/99	Naldini et al.			

FOREIGN PATENTS							
	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	WO 99/31251	06/24/99	PCT				
	WO 99/04026	01/28/99	PCT				
	WO 98/12314	03/26/98	PCT				
	EP 0 759 471 A1-	02/26/97	EPO				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
		Berkhout et al., "Tat Transactivates the Human Immunodeficiency Virus Through a Nascent RNA Target," Cell, 1989, vol. 59: 273-282
		Blomer et al., "Highly Efficient and Sustained Gene Transfer in Adult Neurons with a Lentivirus Vector," Jnl. of Virology, Sept. 1997, vol. 71(9): 6641-6649
		A. Bukovsky et al., "Interaction of Human Immunodeficiency Virus-Derived Vectors with Wild-Type Virus in Transduced Cells," Jnl. of Virology, Aug. 1999, vol. 73(8): 7087-7092
		L-J Chang et al., "Efficacy and Safety Analyses of a Recombinant Human Immunodeficiency Virus Type 1 Derived Vector System," Gene Therapy, 1999, vol. 6: 715-728

EXAMINER:	DATE CONSIDERED:
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.	

\*Substitute Disclosure Statement Form (PTO-1449)

Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE


G&amp;C 131.3-US-WO

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Form 1449* INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION	Docket Number: G&C 131.3-US-WO	Application Number: 10/031,639
	Applicant: Luigi Naldini et al.	
	Filing Date: October 29, 2001	Group Art Unit: To Be Assigned

		JM Coffin, Fundamental Virology, 1996, 3 <sup>rd</sup> Edition (Fields et al., eds), Chapter 26, "Retroviridae: The Viruses and Their Replication," pp. 763-843, Lipincott-Raven Publishers, Philadelphia, PA
		T. Dull et al., "A Third Generation Lentivirus Vector with a Conditional Packaging System," Jnl. of Virology, Nov. 1998, vol. 72(11): 8463-8471
		Elder et al., "Feline Immunodeficiency Virus as a Model for Development of Molecular Approaches to Intervention Strategies Against Lentivirus Infections," Adv. Virus Res., Vol. 45: pp. 225-247
		D. Farson et al., "Large-Scale Manufacturing of Safe and Efficient Rerovirus Packaging Lines for Use in Immunotherapy Protocols," Jnl. of Gene Medicine, 1999, vol. 1: 195-209
		N. Ferry et al., "Liver-Directed Gene Transfer Vectors," Human Gene Therapy, Sept. 1998, vol. 9: 1975-1981
		M. Gasmi et al., "Requirements for Efficient Production and Transduction of Human Immunodeficiency Virus Type 1-Based Vectors," Jnl. of Virology, March 1999, vol. 73(3): 1828-1834
		T. Kafri et al., "Sustained Expression of Genes Delivered Directly Into Liver and Muscle by Lentiviral Vectors," Nature Genetics, Nov. 1997, vol. 17: 314-317
		G. Kalpana, "Retroviral Vectors for Liver-Directed Gene Therapy," Seminars in Liver Disease, 1999, vol. 19(1): 27-37
		Kim et al., "Construction of Retroviral Vectors with Improved Safety, Gene Expression, and Versatility," Jnl. of Virology, Feb. 1998, vol. 72(2): 994-1004
		Lisiewicz et al., "Inhibition of Human Immunodeficiency Virus Type 1 Replication By Regulated Expression of a Polymeric Tat Activation Response RNA Decoy as a Strategy for Gene Therapy in AIDS," Proc. Natl. Acad. Sci. USA, 1993, vol. 90: 8000-8004
		H. Miyoshi et al., "Development of a Self-Inactivating Lentivirus Vector," Jnl. of Virology, Oct. 1998, vol. 72(10): 8150-8157
		L. Naldini et al., "Efficient Transfer, Integration, and Sustained Long-Term Expression of the Transgene in Adult Rat Brains Injected with a Lentiviral Vector," Proc. Natl. Acad. Sci. USA, Oct. 1996, vol. 93: 11382-11388
		L. Naldini et al., "In Vivo Gene Delivery and Stable Transduction of Nondiving Cells by a Lentiviral Vector," Science, April 1996, vol. 272: 263-267
		D. Ory et al., "A Stable Human-Derived Packaging Cell Line for Production of High Titer Retrovirus/Vesicular Stomatitis Virus G Pseudotypes," Proc. Natl. Acad. Sci. USA, Oct. 1996, vol. 93: 11400-11406
		R. Schneider et al., "Inactivation of the Human Immunodeficiency Virus Type I Inhibitory Elements Allows Rev-Independent Expression of Gag and Gag/Protease and Particle Formation," Jnl. of Virology, July 1997, vol. 71(7): 4892-4903

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